



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Numbers AMS-NOP-11-0005; AMS-NOP-11-01]

National Organic Program Regulations; Section 610 Review

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Confirmation of regulations.

SUMMARY: This document summarizes the findings of a USDA Agricultural Marketing Service (AMS) review of the National Organic Program (NOP) which is implemented under the Organic Food Production Act (OFPA). The review criteria are stipulated by the Regulatory Flexibility Act (RFA), in section 610. Based upon this review, the AMS has determined that the USDA organic regulations meet the objectives of the OFPA and should continue. Since becoming effective on the October 21, 2002, there have been multiple amendments to the USDA organic regulations. Most of these amendments were additions to or deletions from the National List of Allowed and Prohibited Substances (National List).

DATES: Effective [Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Interested persons may obtain a copy of the review. Requests for a copy of the review should be sent to Jennifer Tucker, PhD., Acting Director, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW., Room 2648-S., Ag Stop 0268, Washington, DC 20250-0268. Telephone: (202) 720-

3252, Fax. (202) 205-7808 or email: Jennifer.Tucker@ams.usda.gov, or by accessing the Web site at <http://www.ams.usda.gov/nop>.

SUPPLEMENTARY INFORMATION: The National Organic Program (NOP) is authorized by the Organic Foods Protection Act (OFPA) of 1990, as amended (7 U.S.C. 6501 - 6522). The USDA Agricultural Marketing Service (AMS) administers the NOP. Final regulations implementing the NOP were published December 21, 2000 (65 FR 80548), and became effective on October 21, 2002. Through these regulations, the AMS oversees national standards for the production, handling, and labeling of organically produced agricultural products.

The OFPA authorizes the certification and inspection of crop, wild crop, livestock, or handling operations that label, market or represent agricultural products as organic. The OFPA also provides authorization for the NOP to accredit state and private certifying agents to certify organic crop, wild crop, livestock, or handling operations to the USDA organic regulations in the United States and internationally. Since becoming fully effective in 2002, the USDA organic regulations have been frequently amended. Most of these amendments were changes to the National List of Allowed and Prohibited Substances (National List) in 7 CFR 205.601 – 205.606.

This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural, and nonorganic agricultural substances that may be used in organic handling. The OFPA and the NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling appear on the National List.

Recommendations to amend the National List are developed by the National Organic Standards Board (NOSB), a 15-member advisory board composed of four organic farmers; two organic handlers; one retailer; three experts in environmental protection and resource conservation; three consumer or public interest group members; one expert in toxicology, ecology, or biochemistry and; one certifying agent representative. The NOSB is organized under the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.) to assist in the development of standards for substances to be used or not used in organic production and handling, and to advise the Secretary on any other sections of the USDA organic regulations. NOSB members are nominated by the organic community and selected by the Secretary. The OFPA also requires a review of all substances on the National List within 5 years of their addition or renewal. If a substance is not reviewed by the NOSB and renewed through rulemaking by the USDA within the five year period, its allowance or prohibition on the National List is no longer in effect (7 U.S.C. 6517(e)).

As of January 2, 2014, there are 27,108 producer and handler operations certified to the USDA organic regulations. Some of these certified operations are certified as “grower groups,” certified as a single entity, but consisting of groups of ten to thousands of small organic producers. The USDA organic regulations, as authorized by the OFPA, are implemented and applied uniformly and are designed to benefit all entities, regardless of size.

On March 24, 2006, the AMS published in the Federal Register (71 FR 14827), its schedule to review certain regulations, including the NOP, under criteria contained in section 610 of the RFA (5 U.S.C. 601-612). Because many AMS regulations impact small entities, AMS decided, as a matter of policy, to periodically review certain regulations, irrespective of whether specific regulations meet the threshold requirement for mandatory review established by the RFA.

A Notice of Regulatory Flexibility Act: Section 610 Review of the USDA organic regulations was published in the Federal Register on February 25, 2011 (76 FR 10527). This notice indicated AMS would implement specific criteria contained in section 610 of the RFA during the review of the USDA organic regulations that have a significant effect on a substantial number of small entities to determine whether any effect can be decreased or minimized. The purpose of the review is for AMS to determine whether the USDA organic regulations should be continued without change, amended or rescinded, consistent with the objectives of OFPA, to minimize impact on small entities. The review considered these factors: (1) the continued need for the regulations; (2) the nature of complaints or comments received from the public concerning the regulations; (3) the complexity of the regulations; (4) the extent to which the regulations overlap, duplicate, or conflict with other Federal rules, and, to the extent feasible, with State and local government rules; and (5) the length of time since the regulations have been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations. The notice invited the general public and interested parties to submit written comments on the impact of the regulations on small business.

In response to this notice, the NOP received written comments from five organic producers (two crop, one wild crop, and two livestock), three accredited certifying agents, three handlers (an ingredient supplier, a retailer, and a beverage association), two consumers, and an organic business consultant, for a total of fourteen comments.

Of the fourteen comments received, eight commenters specifically addressed the need for the regulations to continue, and not be terminated or rescinded. Five additional commenters proposed amendments or made recommendations about issues for the NOP to consider. One commenter stated that certification of organic products was unfair because of time commitment

and expense. This commenter alternatively proposed that conventional operations should be certified to assess inputs used on these operations. Nine commenters described their concerns with the program or described concerns regarding the regulations. Eight commenters specifically addressed the complexity of the regulations either by indicating that the complexity of the regulations can be problematic at times, or that a significant level of complexity is needed to ensure organic product integrity. There were five comments on whether the regulations overlap, duplicate, or conflict with other Federal, State or Local government regulation. Four commenters specifically addressed the RFA section 610 review criteria regarding impacts on small entities as a result of changes in technology, economic conditions, or other factors that may have impacted an area affected by the regulations since the regulations became effective on October 21, 2002.

One commenter, a certifying agent, addressed all of the factors considered in the RFA section 610 review of the USDA organic regulations. Most of the commenters addressed three out of five of the review factors. Comments are categorically grouped and discussed below.

Comments from organic producers supported continuation of the regulations, but some did include concerns with the program or included proposed amendments for improving it. An organic seed producer expressed support for the continuation of the regulations, but suggested that NOP has not adequately enforced the requirement for the use of organic seed when commercially available as required by 7 CFR 205.204(a). This commenter also suggested that some certifying agents may be routinely allowing the use of non-organic seed, even though high quality organic seed is available in commercial quality and quantity. The commenter requested increased enforcement of the organic seed regulation requirements to ensure organic seed is being utilized by organic producers. In response to comments received at public meetings, the

NOSB provided the NOP with recommendations that outlined concepts and procedures for determining commercial availability of organic seeds and planting stock. In response, the NOP published final guidance NOP 5029: Seeds, Annual Seedlings, and Planting Stock in Organic Crop Production, in the NOP Program Handbook on February 28, 2013.¹ This guidance describes practices for certified operations to use to obtain all organic seeds, annual seedlings, and planting stock in support of their organic production. The guidance also describes the responsibilities of organic operations and certifying agents for sourcing organic seeds and planting stock and emphasizes the utilization of organic seed is a requirement of the regulations.

A certified organic fruit producer commented on being prevented from using an organic label claim on his organic fruit alcohol product because of added sulfites. The commenter stated that because of the restriction with added sulfites limited for use with only organic grapes, a “made with organic...” claim could not be used on the product label. On October 31, 2011, the NOP published Policy Memo 10-2: Sulfur Dioxide in wine made with organic fruit, in the Program Handbook.² This policy memo stipulates that added sulfites, as sulfur dioxide, can only be used in organic wine made from organic grapes as specified on the National List in § 205.605(b). The allowance for sulfur dioxide on the National List limits the use of sulfur dioxide to only wine made with organic grapes and can only be labeled as “made with organic grapes.” Changing the allowance of sulfur dioxide in organic wine can be considered through submission of a National List petition to amend the annotation, and subsequent rulemaking to amend the regulations. As per 7 CFR 205.607 of the USDA organic regulations, any person may

¹ NOP final guidance, instructions, and policy memos can be found in the NOP Program Handbook, available on the NOP Web site at: <http://www.ams.usda.gov/NOPProgramHandbook>.

² Ibid.

submit a petition to change or amend the National List according to petition procedures published on January 18, 2007 (72 FR 2167).³

An organic wild crop producer supported continuation of the regulations, concluding there is an ongoing need for Federal regulation and oversight of the term “organic” as it applies to all products being produced and handled organically. The commenter also stated accredited certifying agents should ensure that organic livestock producers are providing organic livestock with organic feed ingredients. The commenter specifically mentioned organic wild harvested kelp. The commenter claimed ensuring the feeding of organic kelp would enhance his organization’s opportunity to develop and maintain additional certified organic wild crop harvesting sites for kelp, and would support the growth of the business. On February 28, 2013, the NOP published guidance document NOP 5057: The Use of Kelp in Organic Livestock Feed.⁴ This guidance establishes that kelp may be certified organic as a wild crop under 7 CFR 205.207 and must be certified organic if used as an ingredient in livestock feed per § 205.237. The guidance applies to all NOP certifying agents that certify kelp and certified organic operations that feed kelp to organic livestock.

A small livestock producer requested the program increase the \$5,000 exemption limit for organic certification. There is an exemption from certification for organic producers and handlers who sell less than \$5,000 in organic agricultural products per year (7 U.S.C. 6505; 7 CFR 205.101(a)). The livestock producer pointed out that the OFPA was passed in 1990, and the \$5,000 limit has been subject to inflation since 1990. This commenter proposed that the small

³ Notice of Guidelines on Procedures for Submitting National List Petitions, January 18, 2007, available on the NOP Web site:

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=NationalOrganicProgram&leftNav=NationalOrganicProgram&page=NOPFilingaPetition&description=Filing%20a%20Petition>

⁴ NOP 5057: The Use of Kelp in Organic Livestock Feed, available in the NOP Program Handbook on the NOP Web site at: <http://www.ams.usda.gov/NOPProgramHandbook>.

operation exemption be raised to \$10,000 or \$20,000. Since the \$5,000 exemption from certification is a specific OFPA requirement, an increase in the exemption amount must be enacted through Congress and cannot be amended through the regulatory process.

A veterinarian, who also is an organic egg producer, supports the NOP, stating there is a good system of certifiers and inspectors in place. However, this commenter expressed concern with changes in poultry health care practices and living condition standards being advocated by some organizations. The comments addressed issues on poultry access to pasture, animal behavior, bird stocking rate, age of bird, and temporary confinement. According to the commenter, changes in the organic standards on these issues should be based upon scientific merit, and not on human desires and social interactions. During NOSB deliberations, the NOSB considered technical information on livestock practice standards. In 2009 and 2011, the NOSB forwarded several recommendations on establishing more specific animal welfare requirements. These recommendations addressed issues on animal handling and transport and animal welfare, including stocking rates and livestock health care. The NOP is currently evaluating these recommendations to determine how to effectively process these recommendations through rulemaking.

Three accredited certifying agents provided comments in support of continuation of the regulations. A small accredited certifying agent commented on the burden of the expense of the periodic USDA-required accreditation audits on small organic certifiers and requested that audit fees should be scaled upon the size of the certifier. The two larger certifying agents also commented on the paperwork burden on operations seeking certification or continuing with certification. One certifying agent affirmed the need for regulations as critical to assure integrity and maintain consumer confidence in the organic industry. However, comments received from

clients regarding the regulations were mostly concerned with the amount of paperwork required for recordkeeping, which some considered to be excessive and burdensome. This certifying agent stated there is a need to streamline paperwork and recordkeeping requirements for all organic operations. Another certifying agent also addressed the burden faced by certified operations, specifically organic dairy operations complying with pasture practice standards. This commenter stated that the pasture practice standards rule (75 FR 7154) was not needed, was excessively complex, would cause significant adverse effects for many small farms, and would be difficult for certifying agents to effectively implement. The NOP is aware of the commenter's concerns and notes that the pasture practice standards were developed over a period of five years with input of multiple stakeholders. There were a significant number of oral and written responses submitted during public comment periods associated with the development of this rule. The majority of commenters, including many dairy operations, supported the addition of detailed pasture practice standards.

During NOP trainings for accredited certifying agents conducted in 2012 and 2013, the NOP received statements from certifying agents on farmers reporting that they are spending too much of their time completing program forms and maintaining program records. As required in 7 CFR 205.103, recordkeeping is essential to ensure organic operations are implementing required organic practice standards. The NOP has considered how to minimize the regulatory burden when implementing the regulations. As a result, the NOP began implementing an initiative in 2013 to identify and remove barriers to certification, to streamline the certification process, to focus enforcement activities, and to work with organic producers and handlers to correct small issues before they become larger issues. When developing this initiative, the NOP outlined five objectives: 1) develop efficient processes by eliminating bureaucratic processes that

do not contribute to organic integrity; 2) streamline recordkeeping requirements to ensure that required records support organic integrity and are not a barrier for farms and businesses to maintain organic compliance; 3) apply common sense to an operation's organic system plans that clearly capture organic practices; 4) implement fair and focused enforcement; and 5) maintain or improve organic integrity by focusing on factors that impact organic integrity. The NOP continues to work with certifying agents to implement these objectives with regard to the recordkeeping and reporting requirements for certifying agents and organic producers and handlers.

Three organic handlers commented on the RFA Section 610 review. An ingredient processor submitted a comment requesting clarification on why non-organic ethanol is not permitted in the U.S. for use in processing organic products. The processor stated that their product, processed with ethanol, was marketed with an organic label in the European Union (EU), where ethanol is allowed for organic processing in the EU regulations. In the U.S., ethanol is available in certified organic, natural, and synthetic forms. The use of certified organic ethanol would be permitted in the production of the processor's product under the USDA organic regulations. Non-organic ethanol is allowed for use in organic crop and livestock production as a sanitizer. Non-organic ethanol cannot be used in organic processing under the USDA organic regulations since it is not included on the National List in either 7 CFR 205.605 or 7 CFR 205.606. Use of non-organic ethanol in organic processing requires amendment of the National List through the petition process to include non-organic ethanol on the National List, and subsequent rulemaking.

A beverage association comment disagreed with Alcohol, Tobacco Tax, and Trade Bureau (TTB) labeling requirements for wine that requires approval for changes to a vintage year

on an organic wine label that was previously approved. This requirement is outside of the scope of the USDA organic regulations. The TTB reviews and approves wine labels, including any requirements for changing the vintage year. Under a Memorandum of Understanding between AMS and TTB, the TTB receives, reviews, and approves or rejects labeling applications for alcohol products bearing an organic claim. TTB has informed the NOP of their change in the TTB list of the allowable revisions that may be made to an approved label without the need for resubmission contained on the TTB Application for and certification of label/bottle approval. TTB removed the caveat that the change in vintage dates did not apply to organic products.

A comment from an organic co-operative retailer supported the continued need for the regulations. The commenter gave a description of the positive impacts of the complexity of the regulation on their business, and emphasized that the regulations do not overlap, duplicate, or conflict with other Federal, state or local rules for the operation.

A comment from a consumer claimed that certification requirements for organic operations are unfair because nonorganic operations are not required to disclose to the public the uses of harmful substances. All food products in the normal stream of commerce are subject to Federal, state, and local laws and regulatory requirements that contribute to maintaining food safety and restrict or prohibit the use of harmful substances.

Another consumer comment expressed support for continuation of the regulations. This commenter chooses organic products to assure that the food is raised humanely and without synthetic ingredients. However, the commenter also expressed concern that the regulations may be more burdensome to small dairy operations. As noted in prior discussion, the NOP started an initiative on 2013 to reduce the regulatory burden on organic operations.

An organic agricultural business expressed strong support for continuation of the regulations. This commenter stated that the regulations need to be routinely amended since organic production is based upon a concept of continual improvement, and the regulation should adhere to this principle. Such amendments should take into account innovations and improvements by organic practitioners. The commenter proposed several amendments to the regulations, some of these proposed amendments were identified as opportunities to decrease regulatory complexity and reduce regulatory burden without sacrificing organic integrity or compromise consumer confidence. A summary of these proposed amendments include:

- The NOP should prohibit blending of organic and non-organic forms of the same ingredient in “made with organic” products. On May 2, 2014, the NOP published final guidance NOP 5032: Products in the “made with Organic *** Labeling Category to address this issue.⁵ This guidance describes requirements for products in the “made with organic (specified ingredients or food group(s))” category. This guidance clarifies product composition, labeling claims, use of organic and nonorganic forms of the same ingredient, percentage of organic ingredient statements, and ingredients or food groups in the “made with organic ***” claim.
- The regulations should allow the use of non-synthetic substances allowed for use in crop production to control pest infestation in post-harvest handling pest control when preventive practices are ineffective. On April 25, 2014, the NOP published draft guidance, NOP 5023: Substances Used in Post-Harvest Handling of Organic Products.⁶

This draft guidance describes substances that may be used in post-harvest handling of

⁵ NOP 5032: Products in the “made with Organic *** Labeling Category, available in the NOP Program Handbook on the NOP Web site at: <http://www.ams.usda.gov/NOPProgramHandbook>.

⁶ Draft Guidance NOP 5023: Substances Used in Post-Harvest Handling of Organic Products. NOP draft guidance can be found on the NOP Web site at: <http://www.ams.usda.gov/NOPDraftGuidance>.

organic products. The guidance clarifies: 1) what substances may be used; 2) the difference between post-harvest handling of raw agricultural crops and further processing; and 3) the provisions for facility pest management.

- The NOP should amend 7 CFR 205.237(a) to allow commercial availability to be applied to minor agricultural ingredients fed to organic livestock to alleviate burden on small organic livestock producers. On February 28, 2013, the NOP published NOP 5030, Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed.⁷ This guidance clarifies the agricultural, nonsynthetic, and synthetic ingredients permitted in organic livestock feed and also addresses the feed supplements and feed additives that must be reviewed for compliance with regulations. Under the USDA organic regulations, organic producers must provide livestock feed pursuant to 7 CFR 205.237. Section 205.237 states that agricultural ingredients included in the ingredients list for livestock feed products must be organically produced.
- The NOP should amend the National List petition procedures and processes as they are complicated, costly, lengthy, arbitrary, and may not provide due process to the petitioners. In May 2014, the NOP in collaboration with the NOSB initiated a process to revise National List petition procedures in an effort to make the petition submission procedures clearer for petitioners. The revised procedures will clarify how to submit complete petitions, explain to petitioners what to expect in the petition process, and make the review process for the NOSB clearer and more consistent.
- The NOP should increase collaboration between NOP and other government agencies with authority related to organic agricultural production. Historically, NOP has

⁷ NOP 5030: Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed, available in the NOP Program Handbook on the NOP Web site at: <http://www.ams.usda.gov/NOPProgramHandbook>.

established and maintained collaborative interactions with the U.S. Food and Drug Administration (FDA) on organic food processing and handling and livestock healthcare products and feed ingredients; with the U.S. Environmental Protection Agency (EPA) on pest control ingredients and applications; with TTB on labeling of organic alcohol beverages; and with the Federal Trade Commission on product labeling. As part of these interactions, NOP continues to collaborate regarding agricultural products that fall within the scope of organic certification.

- The NOP should alter restrictions on the use of plastic mulch (§ 205.601(b)(2)(ii)) so that biodegradable plastic mulch could remain on the soil beyond harvest or end of the growing season. The commenter indicated there is no listing for mulch made from biodegradable plastic on the National List, and a petition would have to be submitted to add this new material. In August 2013, the NOP published proposed rule (78 FR 52100), based upon NOSB recommendations, which would add a new definition for biodegradable biobased mulch film to 7 CFR 205.2 and add biodegradable biobased mulch film to the National List in 7 CFR 205.601 for use in organic crop production.⁸

Upon the completion of the RFA Section 610 review of the USDA organic regulations, AMS has determined that there is no critical need to amend the regulations. Since becoming effective on the October 21, 2002, there have been multiple amendments of the regulations, mostly to the National List. Some of these amendments have reduced the burden on small operations, while some amendments, that have served to protect organic integrity and support consumer confidence, may have increased the burden on small operations. Based on the findings from the

⁸ National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing); Proposed rule; Available on the NOP Web site: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5104847>

review, AMS has determined that the NOP is not overly complex and does not significantly overlap, or conflict with other regulations.

Based upon the review, AMS has determined that the NOP should continue. The USDA organic regulations are dynamic in nature and the NOP continues to collaborate with the NOSB and the organic community on rulemaking and development of guidance documents, such as recently published rulemaking on pesticide residue testing, and published guidance on composting, wild crop harvesting, handling unpackaged organic goods, and the list of permitted substances for crops.

Authority: 7 U.S.C. 6501-6522.

Dated: April 30, 2015

Rex A. Barnes
Associate Administrator
Agricultural Marketing Service

BILLING CODE 3410-02 P

[FR Doc. 2015-10446 Filed: 5/5/2015 08:45 am; Publication Date: 5/6/2015]